K120645 1/2

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

APR 24 2012

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Pro-Toe™ VO Hammertoe Implant System - Line Addition.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	February 15, 2012
Contact Person:	Ryan Bormann Regulatory Affairs Specialist (901) 867-4409
(a)(2). Proprietary Name:	Pro-Toe™ VO Hammertoe Implant System – Line Addition
Common Name:	Bone Plate System
Classification Name and Reference:	21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HWC: Orthopedic
(a)(3). Predicate Devices:	K101165 – Pro-Toe VO Hammertoe Implant System K022599 – Newdeal® K-Wire

(a)(4). Device Description

The subject implants are modified from the previously cleared Pro-Toe™ VO Hammertoe Implant System. They offer additional size ranges as well as additional material.

(a)(5). Intended Use

The PRO-TOE™ VO Hammertoe Implant system is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

The indications statement is identical to that of the predicate Pro-Toe VO Hammertoe Implant System's.

(a)(6). Technological Characteristics Comparison

While many of the technological characteristics are the same for the subject device system and the predicate, some design changes have been made. The subject implants are intended to offer an extended size range in both length and diameter. In addition to extended sizes, the subject implant has also been developed to offer two different material options for each

size. The previously cleared stainless steel is intended to be offered in all sizes as well as Titanium alloy.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing and engineering analysis supports the equivalence of the new sizes and shows that no new worst-case implants are introduced in this system.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The new design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. Performance testing and engineering analysis shows that no new worst-case design is introduced in this system. Additionally, ASTM standards for the new Titanium address the material change. From the evidence submitted in this 510(k) the subject device system can be expected to perform at least as well as the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Mr. Ryan Bormann
5677 Airline Road
Arlington, TN 38002

APR 2 4 2012

Re: K120645
Trade/Device Name: Pro-Toe VO Hammertoe Implant System – Line Addition
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 24, 2012
Received: March 2, 2012

Dear Mr. Bormann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

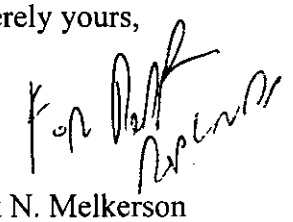
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not yet assigned.~~ K120645

Device Name: Pro-Toe™ VO Hammertoe Implant System – Line Addition

Indications for Use:

The Pro-Toe™ VO Hammertoe Implant System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120645